## REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Appreciation is expressed to Examiner Bouchelle for reconsidering and withdrawing the previous claim rejections.

By this Amendment, Claims 1, 6, 7, 9, 13 and 15 are amended. The claims currently pending in this application are Claims 1-15, with Claims 1, 13 and 15 being the only independent claims. Claim 16 remains canceled.

As discussed previously, independent Claim 1 is directed to a catheter comprising a sheath portion with a lumen extending therein, an insertion member slidably disposed in the lumen and provided with a distal end portion adapted to protrude from the distal end portion of the sheath portion, and an injection needle disposed at the distal end portion of the insertion member for injecting a therapeutic composition to a target tissue. In addition, paired electrodes are disposed in the distal end portion of the catheter for measuring impedance. As set forth in amended independent Claim 1, both of the paired electrodes are disposed at the insertion member apart (spaced) from the bevel of the injection needle, with at least one of the electrodes being constructed to move into the target tissue when the target tissue is punctured by the injection needle.

Addressing independent Claim 1, the Official Action refers to the disclosure in International Application Publication No. WO 99/04851 to *Shapland et al.* *Shapland et al.* discloses an apparatus for delivering an agent directly into a cardiac muscle. The apparatus is provided with an active driver that actively transports the agent to abnormal cardiac tissue. The active driver includes electrodes for performing

iontophoresis which involves the use of two electrodes in intimate electrical contact with a portion of a patient's tissue and a reservoir containing an agent that is to be introduced into the patient's body or tissue. One electrode, referred to as the delivery electrode, is the electrode from which the agent is delivered into the patient's body, while the other electrode, referred to as the return electrode, closes the electrical circuit through the body. The tissue to which the agent is to be delivered (the target tissue) is in the electrical path between the delivery and return electrodes.

The Official Action makes specific reference to the embodiment of the apparatus shown in Fig. 3 of *Shapland et al.*, and the corresponding description in lines 25-28 of page 13 and lines 14 and 15 of page 7. Here *Shapland et al.* describes that the apparatus includes a guiding member 134 such as a catheter, with an inner member 140 slidably received in the guiding member 134. The distal end 145 of the inner member 140 is provided with a needle 148. *Shapland et al.* describes that this needle 148 functions as a first electrode 160. In addition, an un-illustrated electrically conductive band functioning as a second electrode is wrapped around the guiding member 134.

One difference between the claimed catheter recited in independent Claim 1 and the disclosure in *Shapland et al.* is that the claimed catheter comprises paired electrodes for measuring impedance, where both of the electrodes are disposed at the insertion member apart or spaced from the bevel of the injection needle. With both of the electrodes disposed at the insertion member, the distance between the electrodes does not generally change. Thus, a variation in impedance value is generally only caused by the puncture into the tissue and so it is relatively easy to determine whether the puncture has been achieved. In *Shapland et al.*, the first

electrode 160 and the second electrode (i.e., the electrically conductive band wrapped around the guiding member 134) are not both disposed at the inner member 140. Rather, one electrode 160 is provided as a part of the needle bevel while the other is a band on the guiding member 134. With the arrangement disclosed in *Shapland et al.*, as the needle is moved beyond the distal end of the guiding member, there is a possibility that this can cause a change in the impedance values due a change in the distance between the electrodes.

In addition, the electrode 160 that is disposed on the needle in *Shapland et al.* is actually disposed on the bevel of the needle. In contrast, Claim 1 recites that both of the electrodes are disposed at the insertion member apart (spaced) from the bevel of the injection needle. With the arrangement disclosed in *Shapland et al.*, a change in impedance values can occur when the injection needle merely comes in contact with the tissue. On the other hand, by arranging both of the electrodes apart or spaced from the bevel of the injection needle as recited in Claim 1, it is possible to relatively reliably detect when the injection needle has been punctured into the tissue.

For at least the reasons set forth above, it is respectfully submitted that the catheter recited in independent Claim 1 is patentably distinguishable over the disclosure in *Shapland et al.*

The Official Action sets forth a rejection of independent Claim 13 based on the disclosure in *Shapland et al.* in view of the disclosure in U.S. Patent No. 6,391,005 to *Lum et al.* That rejection is also respectfully traversed.

*Lum et al.* discloses an apparatus having a sensor for sensing the depth of penetration of a needle into the tissue of a patient. *Lum et al.* discloses several

embodiments involving a hypodermic needle 110, a solid needle assembly 126 and another hypodermic needle 134. In the case of the hypodermic needle 110 shown in Fig. 2A, the needle is provided with an electrically conductive coating 122 and an electrically conductive wire 120. The solid needle assembly 126 illustrated in Fig. 3 includes a conductive material 130 and a metallic coating 132. The hypodermic needle 134 shown in Fig. 4 includes an inner electrically conductive tubing 136 and an electrically conductive coating 142.

The Official Action refers to *Lum et al.'s* disclosure of an arrangement for sensing penetration depth and concludes that it would have been obvious to utilize such an arrangement in the apparatus disclosed in *Shapland et al.* However, the electrodes disclosed in *Shapland et al.* are not at all used for detecting penetration into patient tissue which is the reason disclosed in *Lum et al.* for utilizing the disclosed arrangement. That is, *Shapland et al.* utilizes the disclosed electrode arrangement (the first electrode 160 on the needle bevel and the second electrode wrapped around the guiding member 134) specifically for purposes of actively transporting angiogenesis agents into the cardiac muscle as discussed beginning at the bottom of page five of *Shapland et al.* Thus, one of ordinary skill in the art would not have been motivated to utilize *Lum et al.'s* puncture detection arrangement in *Shapland et al.'s* apparatus because *Shapland et al.* utilizes the disclosed electrodes for a completely different and unrelated purpose.

In addition, even if one was somehow motivated to carry out the modification proposed in the Official Action, the result would not be that which is recited in independent Claim 13. The reason is because *Lum et al.*, like *Shapland et al.*, discloses that the electrically conductive parts extend into the bevel of the needle.

Thus, combining the disclosures in *Shapland et al.* and *Lum et al.* would not have resulted in paired electrodes disposed at an insertion member apart (spaced) from the bevel of the injection needle as recited in independent Claim 13. It is thus respectfully submitted that independent Claim 13 is also allowable.

The Official Action relies upon the disclosure in U.S. Application Publication No. 2002/018338 to *Chee et al.* and the disclosure in *Shapland et al.* in addressing independent Claim 15. *Chee et al.* discloses various embodiments of an apparatus for guided interventional procedures. By way of example with reference to Fig. 12A, the apparatus includes a distal end probe 130 provided with electrodes 136, 138, 140 and a needle 134 slidably positioned within the distal end probe 130.

The Official Action states that *Chee et al.* discloses a method similar to Claim 15, except that *Chee et al.* does not disclose providing an electrode relative to a bevel of a needle as claimed. The Official Action thus relies upon the disclosure in and thus relies upon the disclosure in *Shapland et al.* It appears there may be a misunderstanding concerning the *Chee et al.'s* disclosure.

As mentioned above, *Chee et al.* discloses providing electrodes (e.g., 136, 138, 140) on the distal end of a distal end probe 130. In addition, a needle 134 is slidably positioned within the distal end probe 130. The purpose for the electrodes 136, 138, 140 is to detect contact with the patient's tissue as described in paragraph [0119]. In addition, *Chee et al.* is interested in determining the angle of contact between the probe 130 and the tissue as mentioned in paragraph [0121]. Once the desired degree of contact or angle of contact is achieved, the needle 134 is advanced relative to the probe to penetrate the patient's tissue.

Thus, considering the purpose served by the electrodes (e.g., 136, 138, 140) described in *Chee et al.*, it would not have been obvious to move *Chee et al.'s* electrodes to in the manner suggested in the Official Action. Indeed, moving the electrodes in the manner proposed in the Official Action would not allow the electrodes to perform the intended function described in *Chee et al.* (i.e., determining the degree or angle of contact of the probe tip with the patient tissue before the needle is advanced into the tissue).

Claim 15 is allowable for other reasons as well. The Official Action states that *Chee et al.* discloses puncturing target tissue based on measurements from electrodes. In this regard, the Official Action specifically references Claims 50 and 52 of *Chee et al.* However, Claim 50 of *Chee et al.* merely describes the tissue-contact sensor (e.g., 136, 138, 148) that is used to detect contact with the tissue surface., and Claim 52 describes the needle (e. g., 134) that is used to penetrate the cardiac tissue and deliver the tissue-damaging fluid.

Contrary to the observation in the Official Action, Claims 50 and 52 do not define a method that involves inserting a catheter into a living body to the neighborhood of a target tissue, measuring impedance with paired electrodes disposed at an insertion portion (i.e., an insertion portion having an injection needle disposed at its distal end) apart (spaced) from the bevel of the injection needle, moving the insertion member relative to a sheath portion, protruding the injection needle from the distal end portion of the sheath portion to puncture target tissue while moving one of the paired electrodes into the target tissue, and injecting therapeutic composition through the injection needle into the target tissue after a change is detected in the impedance values by the paired electrodes. As discussed

at, for example, paragraph [0119] of *Chee et al.*, the sensors 136, 138, 140 disposed on the end of the distal end probe 130 detect surface contact with a patient's tissue, whereupon the needle 134 is then advanced relative to the distal end probe to inject the tissue-damaging agent. Thus, the sensors 136, 138, 140 are not used in such a way that fluid is injected through the needle 134 after a change is detected in the impedance values as measured by the sensors once one of the sensors is moved into the target tissue.

Further yet, neither *Shapland et al.* nor *Chee et al.* discloses a method that utilizes an insertion member slidably disposed in a sheath portion, with paired electrodes disposed at the insertion member apart or spaced from the bevel of the injection needle as set forth in Claim 15.

It is thus respectfully submitted that the method recited in independent Claim 15 is also allowable.

The dependent claims are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the additional distinguishing aspects recited in the dependent claims is not set forth at this time.

Early and favorable action with respect to this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful

in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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